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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,080	04/27/2001	Wendy Naimark	00-0238	1601

27774 7590 07/16/2002

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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,080	Applicant(s) NAIMARK ET AL.	
	Examiner Dave Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 2, 3, drawn to a method of using microparticles to protect pharmaceutical effectiveness of a pharmaceutically active agent when exposed to a metal, classifiable in class 424, subclasses 468, 486.

Group II. Claims 4, 5, drawn to a method of using microparticles to protect pharmaceutical effectiveness of a pharmaceutically active agent when exposed to a polymer, classifiable in class 424, subclasses 468, 497.

Group III, claim 6, drawn to a method of using microparticles to protect pharmaceutical effectiveness of a pharmaceutically active agent when exposed to a freeze-thaw cycle, classifiable in class 424, subclasses 468, 486.

Claims 1, 7-17 link inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 7-17. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group IV, claims 18-24, drawn a method of treatment of pareterally injectiving a medical device having a component that is compatible with a pharmaceutically active agent in combination with the agent and microparticles to any subject so as to treat any medical disease or disorder, classifiable in class 514,

subclass 44.

Group V, claims 25-31, drawn to a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and microparticles, classifiable in class 424, subclass ~~826~~ 462.

Group VI, claims 32-36, drawn to a device for pareteral injection comprising a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and microparticles, a device component that contacts said suspension and is compatible with said pharmaceutically active agent; and a separator, said separator acting to remove said microparticles from said pharmaceutically acceptable suspension prior to parenteral injection, classifiable in class 424, subclass ~~499~~ 484 ; subclass 424.

The inventions are distinct, each from the other because of the following reasons:

Group I, Group II, and Group III are distinct because the methods of Groups I, II, III, and IV are directed to materially distinct steps, *e.g.,* exposing to a metal, exposing to a polymer, or exposing to freeze thaw cycles, wherein the steps generate distinct functions and effects.

Groups I, II, III, and Group IV are distinct because Group IV is directed to distinct goal and materially distinct steps, *e.g.,* treatment of any subject having any medical disease, subjects having any medical diseases, the use of a medical device, and the step of parentally injecting the device for generating a treatment effect within the context of the as-filed specification.

In addition, Group V and Group VI are distinct because the suspension of Group V does not require any medical device and/or any separator as claimed in Group VI, and the suspension of Group V can be used alone in one of the intended utilities as defined by the as-filed specification, *e.g.,* Group I claims.

In addition, Groups I, II, III, IV, and Groups V and IV are distinct because the suspension is not required for used in any of the methods of Groups I, II, III and IV, and can be used alone as a controlled release composition for the control of the delivery of the agent to an intended target site. Further, the

medical device of Group IV is not claimed in any of the methods of Group I, II, III, and IV and the claimed methods are not required to employ the medical device of Group VI which is intended for a distinct goal of removing microparticles from the claimed suspension prior to parenteral injection. As the result, a search for prior art and consideration of patenability of all claims does not necessarily overlap with one another, thereby generating an undue burden on the examiner.

Should Group I be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named metal as listed in claim 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should Group II be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named polymer as listed in claim 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should Group I, II, III, IV, or V be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A cell comprising a polynucleotide;

A plasmid comprising a polynucleotide;

A viral vector comprising a polynucleotide, which is further required to for a species restriction between an adenoviral vector and an AAV vector (see claim 15, for example).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should Group IV or VI be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A syringe or a vascular catheter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species as listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER